(1)

88-20
No.

Supreme Court, U.S.
FILED
JUN 22 1988
JOSEPH F. SPANIOL, JR.
CLERK

IN THE
SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1987

JAMES A. BRADSHAW,
Petitioner,

v.

THE UNITED STATES OF AMERICA,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT ATLANTA, GEORGIA

CHARLES FOSTER COX
COURBOIS and COX
Attorneys at Law
500 N.W. 13th Street
Oklahoma City, Oklahoma 73103
(405) 235-7507
Attorney for Petitioner

QUESTION PRESENTED FOR REVIEW

1) Whether the "intent" requirement of Title 21 U.S.C. Section 333(b) encompasses an intent to defraud or mislead a government agency, or is limited to an intent to defraud or mislead consumers.

2) Whether the indictment in Petitioner's case is so insufficient as to violate his rights under the Fifth and Sixth Amendments to the United States Constitution as well as Rule 7(c)(1) of the Federal Rules of Criminal Procedure.

TABLE OF CONTENTS

	Page
QUESTIONS PRESENTED FOR REVIEW . . .	i
TABLE OF AUTHORITIES	iv
OPINION BELOW AND STATEMENT OF JURISDICTION.	22
RELEVANT STATUTORY PROVISIONS . . .	2, 3
STATEMENT OF THE CASE	3
REASONS FOR GRANTING THE PETITION . .	10
PROPOSITION I:	
IN RULING THAT 21 U.S.C. SECTION 333(b) ENCOMPASSES AN INTENT TO DEFRAUD OR MISLEAD GOVERNMENTAL ENFORCEMENT AGENCIES, THE COURT OF APPEALS FOR THE ELEVENTH CIRCUIT HAS DECIDED AN IMPORTANT QUESTION OF FEDERAL LAW WHICH HAS NOT BEEN, BUT SHOULD BE, SETTLED BY THE SUPREME COURT OF THE UNITED STATES	10

TABLE OF CONTENTS

Page

PROPOSITION II:

PETITIONER'S INDICTMENT IS SO INSUFFICIENT AS TO BE VIOLATIVE OF HIS RIGHTS UNDER THE FIFTH AND SIXTH AMENDMENTS TO THE UNITED STATES CONSTITUTION AND IN VIOLATION OF RULE 7(c)(1) OF THE FEDERAL RULES OF CRIMINAL PROCEDURE. 15

CONCLUSION 22

CERTIFICATE OF SERVICE 23

APPENDIX A. 1a

OPINION OF THE COURT OF APPEALS FOR THE ELEVENTH CIRCUIT 1a

TABLE OF AUTHORITIES

CASES

	Page
Cochran and Sayre v. United States, 157 U.S. 286, 290 (1985)	19
Kordel v. United States, 335 U.S. 345 (1948).	14
Russell v. United States, 369 U.S. 749, 82 S.Ct. 1038, 8 L.Ed.2d 240 (1962)	18
United States v. Abbott Labs, 505 F.2d 565 (4th Cir. 1974)	12
United States v. Criukshank, 92 U.S. 542, 558 (1972)	18
United States v. Debrow, 346 U.S. 374, 377-378 (1953)	19
United States v. Dotterweich, 320 U.S. 277 (1943).	14
United States v. Dr. David Roberts Veterinary Co., 104 F.2d 785 (7th Cir. 1939)	12
United States v. Haga, 821 F.2d 1036 (1987)	13
United States v. Industrial Labs Co. and D. Ochs, 456 F.2d 908 (10th CA 1972)	12
United States v. J. Bernett, 252 F.2d 252 (5th Cir. 1979)	12

TABLE OF AUTHORITIES

CASES

	Page
United States v. Jamieson-McKames Pharmaceutical, et al., 651 F.2d 531 (8th Cir. 1981)	12
United States v. Simmons, 96 U.S. 360 (1877)	18
United States v. Sullivan, 332 U.S. 689 (1948).	14

STATUTES

Title 18 U.S.C. Section 1	10
Title 18 U.S.C. Section 371	13
Title 21 U.S.C. Section 331(a)	3,4,6,10, 11,12,13, 17,19
Title 21 U.S.C. Section 333(a)	3,10,11, 13,20
Title 21 U.S.C. Section 333(b)	3,4,6,7, 8,10,11,12, 13,14,17,20
Title 21 U.S.C. Section 353	11
Title 28 U.S.C. 1254(1)	2
Rule 7(c)(1) F.R.Crim.P.	18
Fifth Amendment to the United States Constitution	17
Sixth Amendment to the United States Constitution	17

IN THE
SUPREME COURT OF THE UNITED STATES
OCTOBER TERM, 1987

No. _____

JAMES A. BRADSHAW,
Petitioner,

v.

THE UNITED STATES OF AMERICA,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT ATLANTA, GEORGIA

The Petitioner, James A. Bradshaw, by and through his attorney, Charles Foster Cox, prays that a Writ of Certiorari issue to review the judgment of the United States Court of Appeals for the Eleventh Circuit in this matter.

OPINION BELOW AND STATEMENT OF JURISDICTION

The decision of the United States Court of Appeals for the Eleventh Circuit from which the certiorari is sought was reported as United States of America v. Bradshaw, 840 F.2d 871 (C.A. 11 Cir. 1987). See Appendix A. This Opinion was issued on March 25, 1988, and the Court's mandate was issued on April 20, 1988. On May 25, 1988, upon request of Petitioner, the Honorable Justice Anthony M. Kennedy entered an Order Extending Time To File Petition for Writ of Certiorari to and including June 23, 1988. The jurisdiction of this Court is invoked pursuant to 28 U.S.C. Section 1254(1).

RELEVANT STATUTORY PROVISIONS

The Petitioner was convicted of violating the Federal Food, Drug and Cosmetic Act contained at 21 U.S.C. Sections 301-392.

The specific portions of said Act which are relevant to this Petition are:

Title 21 U.S.C. Section 331: Prohibited Acts:

"The following acts and the causing thereof are hereby prohibited:

a) The introduction of delivery for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded."

and:

Title 21 U.S.C. Section 333: Penalties:

"a) Violation of 21 U.S.C. Section 331. Any person who violates a provision of section 301 [21 U.S.C. Section 331] shall be imprisoned for not more than one year or fined not more than $1,000, or both.

b) Second offenses; intent to defraud or mislead. Notwithstanding the provisions of subsection (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000 or both."

STATEMENT OF THE CASE

On May 15, 1986, the grand jury for the United States District Court for the Southern District of Florida, which has original jurisdiction over all offenses against the United States of America in that District, returned an indictment

charging Petitioner with twenty-one (21) counts of introducing a misbranded prescription drug into interstate commerce with the intent to defraud or mislead, and two (2) counts of introducing a misbranded veterinary prescription drug into interestate commerce with the intent to defraud or mislead, all in violation of Title 21, United States Code, Sections 331(a) and 333(b).

On October 21, 1986, upon Petitioner's plea of not guilty to all counts of the indictment, a jury was selected and sworn and trial began. On October 23, 1986, the jury returned guilty verdicts on Counts I-XXI of the indictment, and not guilty verdicts on Counts XXII and XXIII.

On December 5, 1986, Petitioner was sentenced to consecutive two (2) year sentences on Counts I, II, and III, concurrent two (2) year suspended sentences on Counts IV-XXI and aggregated Ten Thousand Dollars ($10,000.00) fines on each of the twenty-one counts. In addition, Petitioner was sentenced to a three (3) year probationary term consecutive to the period of confinement, and a total of One Thousand Fifty Dollars ($1,050.00) in special assessments. Thus, Petitioner's aggregate sentence was six (6) years

confinement, three (3) years probation, Two Hundred Ten Thousand Dollars ($210,000.00) in fines and One Thousand Fifty Dollars ($1,050.00) in assessments.

Notice of Appeal was timely filed on December 9, 1986. Petitioner was freed on a One Hundred Thousand Dollars ($100,000.00) appeal bond.

Petitioner's convictions were appealed to the United States Court of Appeals for the Eleventh Circuit. After hearing oral arguments in August of 1987, the Court of Appeals, on March 25, 1988, affirmed Petitioner's convictions. The judgment of the Court of Appeals was issued as mandate on April 20, 1988.

On May 23, 1988, the Petitioner filed an Application for Extension of Time in Which to File Petition for Writ of Certiorari, which, on May 25, 1988, was granted by the Honorable Justice Anthony M. Kennedy. An extension was granted until June 23, 1988 to file his Petition for Writ of Certiorari.

In the indictment, the Petitioner was charged with operating an illegal wholesale drug business. He was accused of selling drugs known as "steroids" through the

mails to customers without prescriptions, which constitutes "misbranding" under the Food, Drug and Cosmetic Act. He was further charged with having done so with the intent "to defraud or mislead", which, under 21 U.S.C. Section 333(b), constituted a felony. He additionally was charged with, but was acquitted of, two counts of selling prescription veterinary drugs through the mails with the intent to defraud or mislead. The primary issue at trial was who must have been defrauded or misled in order for the misdemeanor act of misbranding to be punished as a felony.

At trial, the Petitioner did not deny that he had sold drugs by mail to customers without prescriptions, a violation of 21 U.S.C. Section 331(a). Petitioner further did not deny that he had taken various steps to avoid detection, including using mail drops instead of his home address when mailing drugs to customers and receiving shipments from suppliers, using several names for his business, mislabeling package exteriors as vitamins and "Herbalife products", and had employees pick up and deliver packages to carriers. He also did not deny discussions with customers regarding means of avoiding detection.

In the particular transactions for which he stood trial, the Petitioner sold steroid drugs through the mail to a Jon Barton Shields and a [illegible] Perkins. Both customers did not have prescriptions and purchased the steroids for personal use and for resale. Both customers were willing buyers who never felt that Petitioner defrauded or misled them, as they were provided exactly what they ordered from him.

The Petitioner did not deny these particular transactions, or that they constituted misdemeanors under the Federal Food, Drug and Cosmetic Act. His position was, however, that since the customers bought willingly and were not defrauded or misled, the felony penalty provision of 21 U.S.C. Section 333(b) was not triggered and he could, therefore, be convicted only of misdemeanor offenses.

In response to this position, the Government presented an alternative theory of prosecution, claiming that the Petitioner had defrauded or mislead both the Food and Drug Administration and Florida enforcement authorities. The Petitioner filed a motion in limine to prevent the Government from presenting this theory to the jury, but same was denied by the trial court and the Government's theory was presented.

During deliberations, the jury sent back a note asking the Court to clarify what entities could be the object of an intent to defraud or mislead. Over Petitioner's objection, the court further instructed the jury as follows:

> "If you conclude from the evidence as a whole that there was an intent to defraud or mislead any one of the entities, that is, the natural persons, State Agencies, or Federal Government Agency,. . . then you may consider that the necessary intent has been proved."

The jury then returned a general verdict convicting the Petitioner of 21 of the 23 counts against him.

On appeal to the Eleventh Circuit Court of Appeals, the Petitioner alleged, among other errors, that the trial court erred in allowing the jury to consider an alleged intent to defraud state and federal enforcement authorities. In addition, the Petitioner challenged the sufficiency of the indictment and alleged error in the trial court's failure to sustain Petitioner's Motion to Dismiss said indictment. The Court of Appeals affirmed Petitioner's convictions, ruling that the intent requirement of 21 U.S.C. Section 333(b) encompassed an intent to defraud or mislead a government enforcement agency. Petitioner's challenge to the

sufficiency of the indictment was ruled to be without merit and not discussed.

REASONS FOR GRANTING THE PETITION

PROPOSITION I

IN RULING THAT 21 U.S.C. SECTION 333(b) ENCOMPASSES AN INTENT TO DEFRAUD OR MISLEAD GOVERNMENTAL ENFORCEMENT AGENCIES, THE COURT OF APPEALS FOR THE ELEVENTH CIRCUIT HAS DECIDED AN IMPORTANT QUESTION OF FEDERAL LAW WHICH HAS NOT BEEN, BUT SHOULD BE, SETTLED BY THE SUPREME COURT OF THE UNITED STATES.

The issues presented to the Court of Appeals for the Eleventh Circuit in Petitioner's appeal were ones of first impression for any federal appellate court. The Petitioner stands before this Court as the only person ever convicted in any United States District Court of a felony violation of Title 21 U.S.C. Section 331(a), as expressed through Title 21 U.S.C. Section 333(b), based upon an intent to defraud or mislead governmental enforcement agencies as opposed to the ultimate consumer.

Title 21 Section 333(a) of the Federal Food, Drug, and Cosmetic Act (hereinafter referred to as "Act") defines a misdemeanor offense under the Act, while Section 333(b) defines a felony offense (see 18 U.S.C. Section 1):

> "(a) Any person who violates a provision of section 331 of this title shall be imprisoned for

> not more than one year or fined not more than $1,000, or both.
>
> (b) Notwithstanding the provisions of subsection (a) of this section, if any person. . . commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both." (Emphasis added.)

Section 331 lists conduct prohibited under the Act, including "the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." 21 U.S.C. Section 331(a). (Emphasis added.) A drug is "misbranded" if, for example, it is a prescription drug intended for human use but is distributed without a prescription. 21 U.S.C. Section 353.

These provisions define distributing drugs in violation of Section 331 at least as a misdemeanor (Section 333(a)) or, if an intent to "defraud or mislead" can be shown as a felony. Section 333(b). Although Section 333(b) does not identify who must be defrauded or mislead in order to trigger the felony provision of the statute, other Circuits construing Section 333(b) have based their decisions on a seller's intent to defraud or mislead purchasers, and not on

the theory that a defendant has defrauded or misled governmental enforcement agencies by evading or violating their regulatory systems. To this extent, the decision of the Court of Appeals for the Eleventh Circuit would seem to be in conflict with these circuits and their opinions in United States v. Jamieson-McKames Pharmeceuticals, Inc., 651 F.2d 532 (8th Cir. 1981), cert. den., 102 S.Ct. 1709 (1982); United States v. Abbott Laboratories, 505 F.2d 565 (4th Cir. 1974), cert. den., 95 S.Ct. 1424 (1975); United States v. Industrial Laboratories Co., 456 F.2d 908 (10th Cir. 1972); United States v. Dr. David Roberts Veterinary Co., 104 F.2d 785 (7th Cir. 1939) and United States v. Jessie Barnett, 587 F.2d 252 (5th Cir. 1978), cert. den., 99 S.Ct. 2031 (1979). While hundreds of cases have been prosecuted in the United States District Courts involving the "misbranding" of foods, drugs, devices or cosmetics under Title 21 U.S.C. Section 331(a), no defendant, save Petitioner, has been found guilty of the felony provision of Title 21 U.S.C. Section 333(b) unless the misbranding involved the intent to defraud or mislead the purchaser by active, intentional deceit. This issue has never been presented to, or decided by, the United States Supreme Court.

Prosecutions involving unlawful distributions of steroids and androgenic hormones are a relatively recent phenomenon. Counsel is aware of but four other cases that have been filed in the United States District Courts seeking felony convictions for misbranding such drugs under 21 U.S.C. Section 331(a). In three of those cases, the accused have plea-bargained for misdemeanor convictions under 21 U.S.C. 333(a). In the fourth case, United States of America v. Haga, 821 F.2d 1036 (1987), the defendant was acquitted in a non-jury trial of the felony provisions of 21 U.S.C. 333(b) and found guilty of the lesser-included misdemeanor provision of 21 U.S.C. Section 333(a) based on essentially the same facts as in Petitioner's case. In Haga, supra, the defendant was found guilty of conspiracy to "commit offenses against the United States" in violation of 18 U.S.C. Section 371, by participating in the sale of steroids without prescriptions in contravention of the Food, Drug, and Cosmetic Act. Haga's felony conviction was reversed by the Court of Appeals for the Fifth Circuit, based on the insufficiency of the indictment charging the conspiracy count, but in its opinion (which did not reach the issue at bar

because Haga had not been found guilty of a 333(b) felony), the Court of Appeals noted that it viewed the district court's rejection of the Section 333(b) felony theory argued by the government at trial as an implied acquittal of charges based on that theory which barred retrial, and commented on the innovative nature of the government's theory of the case which is identical to that advanced in the prosecution of Petitioner.

It is further urged that the opinion of the Court of Appeals for the Fifth Circuit is in conflict with the legislative history of the Act as interpreted by the United States Supreme Court in Kordel v. United States, 335 U.S. 355 (1948); United States v. Dotterweich, 320 U.S. 277 (1943) and United States v. Sullivan, 332 U.S. 689 (1948), and is inconsistent with the prosecutorial history of the Act over the entire term of its existence.

Inasmuch as the Court of Appeals for the Fifth Circuit has decided an important question of federal law which has not been, but should be, settled by the United States Supreme Court, and has rendered an opinion in conflict with opinions of several other Circuit Courts of Appeal, as well

as the legislative and prosecutorial history of the Act, it is urged that the Supreme Court of the United States should grant the Petition and determine this important federal question.

PROPOSITION II

PETITIONER'S INDICTMENT IS SO INSUFFICIENT AS TO BE VIOLATIVE OF HIS RIGHTS UNDER THE FIFTH AND SIXTH AMENDMENTS TO THE UNITED STATES CONSTITUTION AND IN VIOLATION OF RULE 7(c)(1) OF THE FEDERAL RULES OF CRIMINAL PROCEDURE.

The indictment returned against Petitioner in the United States District Court for the Southern District of Florida states, in pertinent part:

> "1. JAMES BRADSHAW, an individual, defendant herein, was engaged in the business of promoting, purchasing, holding, packaging, shipping, selling, and introducing into interstate commerce certain prescription drugs to lay persons without prescriptions. Defendant was at all relevant times operating in the Southern District of Florida, and doing business under the following names: James Pharmaceuticals, Nauctical Systems, Elite Enterprises, RICO, Mail Answer, JAB, Inc., JBA, Jim Bradshaw, and JBA, Inc.
>
> 2. Anabolic steroids, androgenic hormones, and other human prescription drugs are drugs within the meaning of Title 21, United States Code,

Section 321(g)(1)(C), and further are prescription drugs within the meaning of Title 21, United States Code, Sections 353(b)(1)(B) and (C), in that these drugs are not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. The anabolic steroids described hereafter are oxandrolone, methandrostenolone, stanozolol, nandrolone decanoate, and ethylestrenol. The androgenic hormones described hereafter are testosterone enanthate, fluoxymesterone, testosterone cypionate, and methyltestosterone. The other prescription drugs described hereafter are chormonic gonadotropin, levodopa, furosemide, and crescormin. Veterinary anabolic steroids are animal drugs within the meaning of Title 21, United States Code, Section 321(w)(1). The veterinary anabolic steroid described hereinafter is boldenone undecylenate.

3. On or about April 4, 1985, within the Southern District of Florida, defendant JAMES BRADSHAW, did, with the intent to defraud and mislead, introduce and deliver, and cause to be introduced and delivered for introduction into interstate commerce, METHANDROSTENOLONE, a drug, to Susan Perkins, at Oklahoma City, Oklahoma, which drug was a prescription drug, within the meaning of Title 21, United States Code, Sections 353(b)(1)(B) in that its toxicity and other potentiality for harmful effect, and the method of its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; and (C) it is limited by an approved application to use under the professional supervision of a practitioner licensed by law to administer such drug; and such drug was misbranded within the meaning of Title 21, United States Code, Section 353(b)(1), in that the drug was dispensed without a prescription of

> a practitioner licensed by law to administer such drug. All in violation of Title 21, United States Code, Sections 331(a) and 333(b)."

Other counts in the indictment allege essentially the same acts with different purchasers and drugs. Nowhere in the indictment is there mentioned an intent to defraud or mislead governmental enforcement agencies, either state or federal.

The Fifth Amendment to the United States Constitution requires that a grand jury determine whether an indictment should be handed down. From the face of the indictment, it is impossible to determine with fair certainty that the grand jury in Petitioner's case determined that there were grounds to indict Petitioner for intending to defraud or mislead any governmental agency, as none are mentioned. The Sixth Amendment requires that "the accused shall enjoy the right. . . to be informed of the nature and cause of the accusation. . . ". The primary purpose of an indictment is to provide a defendant with adequate notice of the crime with which he is charged and notify him of all the legal elements and essential facts in a way that will enable him to prepare for trial. This

fundamental principle, advanced by this Court in United States v. Simmons, 96 U.S. 360 (1877), is violated by the opinion of the Court of Appeals for the Eleventh Circuit in ruling that the indictment at bar was sufficient. Even though the indictment charges the essential elements of the offense, there are insufficient facts plead to make certain that the defendant is not tried upon a theory or evidence which was not fairly embraced in the facts upon which the grand jury based its charges, in violation of Russell v. United States, 369 U.S. 749, 82 S.Ct. 1038, 8 L.Ed.2d 240 (1962).

A second purpose of an indictment is "to inform the Court of the facts alleged, so that it may decide whether they are sufficient in law to support a conviction if one should be had." United States v. Cruikshank, 92 U.S. 542, 558 (1972); Russell v. United States, supra, 369 U.S. at 760, n.15. Rule 7(c) of the Federal Rules of Criminal Procedure requires the Government to plead essential facts sufficient to apprise the defendant of the offense charged and to enable the court to determine whether the facts alleged are sufficient to withstand a motion to dismiss the indictment or to support a conviction, and not mere legal conclusions.

It is also essential that an indictment be specific and definite enough to protect the defendant from multiple prosecutions for the same alleged offense. The indictment must sufficiently outline the details of the offense charged so that "in case any other proceedings are taken against him for a similar offense. . . the record shows with accuracy to what extent he may plead a former acquittal or conviction." Cochran and Sayre v. United States, 157 U.S. 286, 290 (1895); United States v. Debrow, 346 U.S. 374, 377-378 (1953). It must specifically set forth the facts which constitute the core of the alleged offense.

It is respectfully urged that while the instant indictment may have alleged the essential elements of the offense charged under 21 U.S.C. Section 331(a), i.e., that Petitioner introduced into interstate commerce a drug that was misbranded on a certain date to a certain person, it is impossible for Petitioner to determine if he was tried upon a theory or evidence which was not fairly embraced in the facts upon which the grand jury based its charges without knowing specifically who he allegedly intended to defraud or mislead. The lack of this specific fact deprived Petitioner

of the opportunity to adequately prepare for trial, in that he was forced to guess whether the grand jury charged him with intending to defraud or mislead Susan Perkins, Jon B. Shields, or some other person or entity. Similarly, the indictment fails to inform the court of the facts alleged in a specific enough manner for it to determine if they are sufficient to support his conviction. At this point, it is impossible to determine if the jury at trial convicted Petitioner of intending to defraud Susan Perkins, Jon B. Shields, the State of Florida, the Federal Government, or someone else. There is no way for the Court to determine if the evidence was sufficient to support a finding of an intent to defraud or mislead without knowing who or what was defrauded or misled. Therefore, this information becomes as crucial as the essential elements of the offense, and constitute the core of the Petitioner's felony conviction under 21 U.S.C. Section 333(b) as opposed to the misdemeanor offense under 21 U.S.C. Section 333(a). In addition, the Petitioner cannot now be certain to what extent he could plead a former conviction in the event any other proceedings are taken against him for a similar

offense. If, for example, the Government should now charge Petitioner with introducing, with the intent to defraud and mislead, misbranded drugs into interstate commerce to some customer other than Susan Perkins or Jon B. Shields, would that prosecution be barred because the intent was to defraud or mislead the State of Florida or the Food and Drug Administration and forms the basis of his present convictions, or allowed, because the intent to defraud or mislead applies to only the two persons named in the present indictment.

It is urged therefore, that inasmuch as the instant indictment fails to perform the vital functions it is intended to guarantee, it is insufficient, and that the opinion of the Eleventh Circuit Court of Appeals is in opposition to established precedent of the United States Supreme Court as heretofore delineated. For this reason, it is urged that the United States Supreme Court review the decision made by the Court of Appeals for the Eleventh Circuit.

CONCLUSION

For the reasons stated, it is respectfully requested that the Petitioner's Petition for a Writ of Certiorari be granted.

Respectfully submitted,

CHARLES FOSTER COX
Courbois and Cox
Attorneys at Law
500 Northwest 13th Street
Oklahoma City, Oklahoma 73103
(405) 235-7507

ATTORNEY FOR PETITIONER

CERTIFICATE OF SERVICE

The undersigned certifies that a true and correct copy of the foregoing PETITION FOR A WRIT OF CERTIORARI was mailed by United States Postal Service certified mail to the offices of the United States Solicitor General, Department of Justice, Washington, D.C. 20530 on the 22nd day of June, 198, and that the Solicitor General is the only party required to be served by the Rules of the United States Supreme Court.

CHARLES FOSTER COX

APPENDIX A

UNITED STATES COURT OF APPEALS,
ELEVENTH CIRCUIT

No. 86-6019

UNITED STATES of America,
Plaintiff-Appellee,

v.

James A. BRADSHAW,
Defendant-Appellant.

[Filed March 25, 1988]

Defendant was convicted by jury in the United States District Court for the Southern District of Florida, No. 86-6113-CR-JCP, James C. Paine, J., of 21 violations of Federal Food, Drug, and Cosmetic Act based on sales of steroids to customers without prescriptions, and he appealed. The Court of Appeals, Anderson, Circuit Judge, held that FDC Act provision making violation of Act a felony if committed with "intent to defraud or mislead" encompassed such intent with respect to state and federal government enforcement agencies, not merely ultimate consumers.

Affirmed.

Drugs and Narcotics

Provision of Federal Food, Drug, and Cosmetic Act making violation a felony for the second offense if it is committed with "intent to defraud or mislead" encompasses such intent with respect to state and federal enforcement agencies, not merely ultimate consumers. Federal Food, Drug and Cosmetic Act, §333(b), 21 U.S.C.A. §333(b).

Appeal from the United States District Court for the Southern District of Florida

Before TJOFLAT and ANDERSON, Circuit Judges, and ROETTGER* District Judge.

*(Honorable Norman C. Roettger, Jr., U.S. District Judge for the Southern District of Florida, sitting by designation.)

ANDERSON, Circuit Judge:

The appellant, James Bradshaw, appeals his conviction for violating the Federal Food, Drug, and Cosmetic Act (the "FDC Act" or the "Act"). 21 U.S.C. §301-392. The various acts that constitute criminal violations of the FDC Act are set forth in 21 U.S.C. §331. All of these violations are misdemeanors regardless of the violator's intent. 21 U.S.C.

§333(a). A violation of the Act becomes a felony if it is a second offense or if it is committed with "intent to defraud or mislead." 21 U.S.C. §333(b). The principal issue on this appeal is whether the intent requirement of §333(b) encompasses an intent to defraud or mislead a government enforcement agency. Because we find that it does, we affirm the conviction of the appellant.

Bradshaw admitted that he operated an illegal wholesale drug business. More specifically, Bradshaw sold drugs widely known as "steroids"[1] (As commonly used, the term "steroids" denotes a large class of prescription drugs, some of which fit the technical definition of steroids and some of which do not. Although apparently not all of the drugs Bradshaw sold would fit the definition of steroids, for the sake of convenience we use the term "steroids" throughout this opinion to refer to all of those drugs) to customers without prescriptions.[2] (21 U.S.C. §331 provides as follows: The following acts and the causing thereof are prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded. Pursuant to 21

U.S.C. §353, a prescription drug dispensed without a prescription is deemed misbranded. Thus, selling prescription drugs without a prescription is a violation of the Act.) Bradshaw's customers were mostly athletes who took steroids to increase muscle mass and thereby improve athletic performance. Although effective for those purposes, the drugs also have many harmful side effects. The Food and Drug Administration ("FDA") has approved the use of steroids for certain medical purposes, but not for the purposes of increasing muscle mass and improving athletic performance.

The FDA first became aware of Bradshaw's business in late 1982. Acting on information from an FDA undercover investigation, Oklahoma authorities arrested Bradshaw in May, 1983. In the course of that arrest, a search of Bradshaw's apartment uncovered over 100 containers of steroids. Bradshaw pled guilty to one state charge growing out of that incident and served no time in prison.

Undeterred by his first brush with the law, Bradshaw continued his wholesale steroid business until the search of his apartment in May, 1985 which led to the charges in this

case. During this period, Bradshaw took various actions to avoid detection. He moved from state to state frequently. He used mail drops rather than his home address when mailing drugs to customers. He repeatedly used false names. He mislabeled his packages as vitamins and "Herbalife products". He hired surrogates to pick up and deliver the packages to carriers. He discussed methods of avoiding detection with his customers.

Just prior to the time of the search, Bradshaw was operating in Florida. In an attempt to obtain a Florida drug wholesaler's permit in the spring of 1984, Bradshaw made affirmative misrepresentations to Florida state drug authorities. He led the authorities to believe that he was an established drug wholesaler in Alabama, and the Florida authorities issued him a permit on that basis. Bradshaw did have a valid Alabama license at the time of his initial Florida application. However, the Alabama license expired during the pendency of the Florida application, and Bradshaw never informed the Florida authorities. Moreover, Bradshaw also led the Florida authorities to believe that he would keep his business in Alabama and only have agents in

Florida. Instead, Bradshaw moved his entire operation to Florida. Because Bradshaw never notified the Florida authorities of the identity of his agents and never had a facility inspected, the Florida permit was never valid.

In the particular transactions at issue here, Bradshaw sold steroids through the mail to Jon Barton Shields and Susan Perkins. Both Shields and Perkins testified that they bought the steroids for personal use and resale. Both Shields and Perkins also testified that although Bradshaw never told them of the side effects of the drugs, they never felt that Bradshaw defrauded or misled them. They were willing buyers, and Bradshaw provided them with exactly what they ordered.

Therein lies the dispute in this case. Bradshaw admits that the transactions took place and that they constituted misdemeanors under the Act. He argues, however, that because Shields and Perkins bought the drugs willingly, he did not intend to defraud or mislead anyone. Therefore, he contends that he cannot be convicted of the felony.[3] (Bradshaw apparently had no prior federal convictions under the FDC Act. For that reason, he could not be charged under the second offense prong of the felony provision.)

Recognizing the problem that Bradshaw's argument presented, the government offered an alternative theory of the case. It claimed that Bradshaw had defrauded or misled both the FDA and the Florida enforcement authorities. Bradshaw filed a motion **in limine** to prevent the government from pursuing its alternative theory before the jury, but the district court denied that motion.

At trial, the judge instructed the jury that it could consider the government's theory. During the deliberations, the jury sent back a note asking the judge to clarify what entities could be the object of an intent to defraud or mislead. Over Bradshaw's objection, the court further instructed the jury as follows:

> If you conclude from the evidence as a whole that there was an intent to defraud or mislead any one of the entities, that is, the natural persons, State Agency, or Federal Government Agency. . . then you may consider that the necessary intent has been proved.

Record on Appeal, vol. 6 at 521. The jury then returned a general verdict convicting Bradshaw of 21 of the 23 counts against him.

The instruction quoted above permitted the jury to return a verdict on any of three grounds: (1) that Bradshaw intended to defraud natural persons[4] (Bradshaw argues that the government did not offer sufficient evidence to prove that he intended to defraud or mislead either John Barton Shields or Susan Perkins, the immediate purchasers in the transactions at issue here. We find that the judge's reference to "the natural persons" was broad enough to encompass the unknown third persons to whom Perkins and Shields planned to resell the drugs. **See Riggs v. United States,** 280 F.2d 750 (5th Cir. 1960) (intent to defraud in statute prohibiting passing of counterfeit currency could extend to unknown future transferees even when the original transferees knew the currency was counterfeit). **Riggs** was decided prior to the close of business on September 30, 1981, and is binding precedent under **Bonner v. City of Prichard,** 661 F.2d 1206, 1209 (11th Cir. 1981). Because the evidence clearly showed that Bradshaw knew that Perkins and Shields bought for the purpose of resale, we have no trouble in ruling that the government offered sufficient evidence for the jury to find that Bradshaw intended to

defraud those unknown third persons to whom Perkins and Shields would resell the drugs); (2) that Bradshaw intended to defraud a state law enforcement agency; or (3) that Bradshaw intended to defraud a federal law enforcement agency. The government concedes that each of these grounds must be sufficient as a matter of law in order for us to uphold Bradshaw's conviction. The government also concedes that the submission of its theory was not harmless if it was error. Bradshaw argues that the trial judge erred in allowing the jury to consider an alleged intent to defraud state and federal enforcement authorities.

We must determine whether the trial judge properly submitted the government's theory to the jury. Bradshaw urges us to construe 21 U.S.C. §333(b) strictly to limit the felony penalty to situations in which the conduct defrauds or misleads the ultimate consumer. In considering Bradshaw's argument, we are mindful that "[t]he starting point of statutory construction is the plain language of the statute itself." **Greyhound Corp. v. Mt. Hood Stages, Inc.**, 437 U.S. 322, 330, 98 S.Ct. 2370, 2375, 57 L.Ed.2d 239 (1978).

We see no indication in the language of the statute or its legislative history that Congress meant to limit the felony penalty to conduct intended to defraud the ultimate consumer to the exclusion of the government enforcement agencies. To the contrary, the structure of the statutory scheme, the purpose of the statute, and the case law persuade us that Congress meant to encompass conduct intended to defraud government enforcement agencies.

As noted at the outset, 21 U.S.C. §331 lists the acts which constitute criminal violations of the Act. Section 333(a) provides that anyone who violates a provision of §331 commits a misdemeanor. Section 333(b) provides that "[n]otwithstanding the provisions of subsection (a) of this section, if any person commits. . . such a violation [i.e., a violation of §331] with intent to defraud or mislead. . . ," he commits a felony.

Several of the acts §331 prohibits concern only the government. For example, §331(p) prohibits the failure to register with the FDA. Other examples include §331(e) (failure to permit FDA access to records and failure to make reports to the FDA) and §331(f) (refusal to permit

FDA inspection). After reading these sections with §333, it is clear that the FDA is the entity most likely to be defrauded under these provisions. Thus, we conclude that Congress intended the "intent to defraud or mislead" language of §333(b) to extend to the FDA.[5] (We also note the Tenth Circuit's decision in **United States v. Cattle King Packing Co.**, 793 F.2d 232 (10th Cir.), **cert. denied**, ____ U.S. ____, 107 S.Ct. 573, 93 L.Ed.2d 577 (1986). Although the defendants did not raise the issue, the court affirmed their felony convictions under similar provisions of the Federal Meat Inspection Act. The defendants were meat packers. Among other things, they were convicted of failing to have meat which had been returned as unfit inspected before reshipping it. In at least one instance, the meat was not reshipped. 793 F.2d at 237-38. In that case, it is difficult to see who was defrauded other than the government.)

The purpose of the statute also supports our conclusion. The general scheme of the Act and its legislative history indicate that the overriding congressional purpose was consumer protection - the protection of the

public against any misbranded or adulterated food, drug, device, or cosmetic. When Bradshaw misled the governmental agencies, thereby frustrating their efforts to protect the public, he indirectly misled and defrauded the public. Thus, Bradshaw's actions fell squarely within the congressional purpose. Bradshaw's arguments that the Act's goal of consumer protection somehow limits the felony penalty to conduct intended to defraud the consumer are unpersuasive. Our result is entirely consistent with that goal.

Finally, although the particular provision at issue here has not been previously interpreted, case law interpreting similar provisions in other statutes is much the same as our interpretation of the FDC Act. For example, in interpreting a similar provision in a counterfeit statute, our predecessor court noted that the statute "uses the comprehensive term 'with intent to defraud' for the very purpose of making it immaterial whether the offender intended to defraud the government or some particular individual." **Bachrack v. United States**, 75 F.2d 824, 824-25 (5th Cir. 1935). We believe that had Congress intended to limit the intent

requirement to an intent to defraud consumers, it would have plainly said so.[6] (Appellant's brief points to no legislative history manifesting any such intent on the part of Congress.)

Courts have repeatedly interpreted analogous provisions to include entities other than those one would normally expect to be the parties defrauded. **Barnett v. United States**, 384 F.2d 848, 854-55 (5th Cir. 1967) (intent to defraud in statute prohibiting alteration of currency extended to coin collectors as well as the government); **Riggs v. United States**, 280 F.2d 750 (5th Cir. 1960) (intent to defraud in statute prohibiting passing of counterfeit currency extended to unknown future transferees and the government as well as the original person to whom the note was passed); **United States v. Rabinowitz**, 176 F.2d 732 (2d Cir. 1949) (intent to defraud in statute prohibiting passing and possessing altered postage stamps extended to private stamp collectors as well as the government), **rev'd on other grounds**, 339 U.S. 56, 70 S.Ct. 430, 94 L.Ed. 653 (1950); **Friedman v. United States**, 5 F.2d 671 (6th Cir. 1925) (intent to defraud in statute prohibiting passing of altered liberty

bonds extended to unknown future transferees as well as the original transferee).[7] (**But see United States v. Grissom**, 645 F.2d 461 (5th Cir. Unit A 1981) (intent to defraud in statute prohibiting unauthorized disposal of FHA-mortgaged property did **not** extend to sharecropper's landlord as well as government). Because **Grissom** was decided on May 20, 1981 it is binding precedent under **Bonner, supra**, footnote 4. **Grissom** does not persuade us because it seems limited to its peculiar facts and because it implicates certain federalism concerns not present here.) Like the courts in these cases, we believe the drafters of the Act left it flexible enough to cover unforeseen situations.[8] (We do not think the recent case of **McNally v. United States**, _____ U.S. _____, 107 S.Ct. 2875, 97 L.Ed.2d 292 (1987), affects the analysis in this case. **McNally** rejected a line of decisions in the several courts of appeals holding that the mail fraud statute protects against schemes to defraud citizens of their intangible rights to honest and impartial government. In **McNally**, the Supreme Court held that the "scheme or artifice to defraud" language of the mail fraud statute referred only to deprivations of money or property, and not

to the intangible right of the citizenry to good government. Unlike the mail fraud statute at issue in **McNally**, the statute involved in the instant case is clearly **not** focused on protecting money or property interests. Rather, the instant statutory scheme is designed to protect the public against any misbranded or adulterated food, drug, device, or cosmetic. **See McNally**, _____ U.S. _____, 107 S.Ct. at 2881 n. 8.) Moreover, courts had already decided **Bachrack, supra**, and **Friedman, supra**, when Congress wrote §333(b) in 1938, further strengthening our interpretation.[9] (Having found that the intent requirement can extend to the FDA, we have little difficulty in finding that it may extend to state drug enforcement authorities as well. The state enforcement authorities work closely with federal authorities in the common goal of protecting the consumer. We do not believe that Congress could have intended to include the FDA and exclude the state drug enforcement authorities. At a minimum, we believe that Congress would have made such an odd intention explicit. By so finding, we do not imply any change in the respective jurisdictional spheres of the state and federal agencies. Rather, we

decide only that the intent requirement in §333(b) may extend to a state enforcement agency as well as a federal agency.)

Bradshaw's other arguments are without merit and warrant no discussion. For the foregoing reasons, the judgment of the district court is

AFFIRMED.

Supreme Court, U.S.
FILED
OCT 7 1988
JOSEPH F. SPANIOL, JR.
CLERK

No. 88-20

In the Supreme Court of the United States

OCTOBER TERM, 1988

JAMES A. BRADSHAW, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

CHARLES FRIED
Solicitor General
JOHN R. BOLTON
Assistant Attorney General
DOUGLAS N. LETTER
GERALD C. KELL
Attorneys

Department of Justice
Washington, D.C. 20530
(202) 633-2217

15 pp

QUESTIONS PRESENTED

1. Whether Section 303(b) of the Food, Drug, and Cosmetic Act, 21 U.S.C. 333(b), makes it a crime to introduce misbranded drugs into interstate commerce, in violation of Section 301(a) of that Act, 21 U.S.C. 331(a), with the intent to defraud or mislead the Food and Drug Administration or a state regulatory agency.

2. Whether the indictment in this case was sufficient to inform petitioner of the charges against him.

TABLE OF CONTENTS

	Page
Opinion below	1
Jurisdiction	1
Statement	2
Argument	4
Conclusion	11

TABLE OF AUTHORITIES

Cases:

Bachrack v. *United States*, 75 F.2d 824 (5th Cir. 1935)	7
Barbee v. *United States*, 392 F.2d 532 (5th Cir.), cert. denied, 391 U.S. 935 (1968)	9, 10
Bartell v. *United States*, 227 U.S. 427 (1913)	10
Garcia v. *United States*, 469 U.S. 70 (1984)	6
Hamling v. *United States*, 418 U.S. 87 (1974)	8-9
Hammerschmidt v. *United States*, 265 U.S. 182 (1924)	5
Kordel v. *United States*, 335 U.S. 345 (1948)	7
Russell v. *United States*, 369 U.S. 749 (1962)	10
United States v. *Abbott Laboratories*, 505 F.2d 565 (4th Cir. 1974), cert. denied, 420 U.S. 990 (1975)	7
United States v. *Bailey*, 444 U.S. 394 (1980)	8
United States v. *Barnett*, 587 F.2d 252 (5th Cir.), cert. denied, 441 U.S. 923 (1979)	7
United States v. *Bernstein*, 533 F.2d 775 (2d Cir.), cert. denied, 429 U.S. 998 (1976)	9
United States v. *Castor*, 558 F.2d 379 (7th Cir. 1977), cert. denied, 434 U.S. 1010 (1978)	9
United States v. *Cattle King Packing Co.*, 793 F.2d 232 (10th Cir.), cert. denied, 479 U.S. 985 (1986)	7
United States v. *Crippen*, 579 F.2d 340 (5th Cir. 1978)	9
United States v. *Dotterweich*, 320 U.S. 277 (1943)	6
United States v. *Dr. David Roberts Veterinary Co.*, 104 F.2d 785 (7th Cir. 1939)	7
United States v. *Haga*, 821 F.2d 1036 (5th Cir. 1987)	7, 8

Cases—Continued: Page

United States v. *Jamieson-McKames Pharmaceuticals, Inc.*, 651 F.2d 532 (8th Cir. 1981), cert. denied, 455 U.S. 1016 (1982) 8
United States v. *Lavergne*, 805 F.2d 517 (5th Cir. 1986) .. 9
United States v. *Sullivan*, 332 U.S. 689 (1948) 6, 7
Weinberger v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973) 6

Statutes:

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. (& Supp. IV) 301 *et seq.*:
§ 301, 21 U.S.C. (& Supp. IV) 331 ..... 2, 4, 8
§ 301(a), 21 U.S.C. 331(a) 2
§ 301(b), 21 U.S.C. 331(b) 9
§ 301(p), 21 U.S.C. 331(p) 6
§ 303(a), 21 U.S.C. 333(a) 2, 4
§ 303(b), 21 U.S.C. 333(b) 2, 3, 4, 5, 6, 7, 9
§ 503(b)(1), 21 U.S.C. 353(b)(1) 2
§ 503(b)(1)(B), 21 U.S.C. 353(b)(1)(B) 2
§ 503(b)(1)(C), 21 U.S.C. 353(b)(1)(C) 2
Federal Meat Inspection Act, 21 U.S.C. (& Supp. IV) 601 *et seq.*:
21 U.S.C. (& Supp. IV) 601-624 7
21 U.S.C. (& Supp. IV) 661-680 7
21 U.S.C. 676(a) 7
Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, 102 Stat. 95:
§ 7(b), 102 Stat. 99 (codified at 21 U.S.C. 333(a)(1) and (2)) 2
§ 8, 102 Stat. 100-101 2
18 U.S.C. 472 ..... 7, 10

Miscellaneous:

131 Cong. Rec. (daily ed. Sept. 22, 1988):
p. H7906 8
p. H7908 8
H.R. 5210, 100th Cong., 2d Sess. (1988) 8
1 C. Wright, *Federal Practice and Procedure* (2d ed. 1982) 10

In the Supreme Court of the United States

OCTOBER TERM, 1988

No. 88-20

JAMES A. BRADSHAW, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINION BELOW

The opinion of the court of appeals (Pet. App. 1a-16a) is reported at 840 F.2d 871.

JURISDICTION

The judgment of the court of appeals was entered on March 25, 1988. On May 25, 1988, Justice Kennedy extended the time within which to file a petition for a writ of certiorari to and including June 23, 1988. The petition for a writ of certiorari was filed on June 22, 1988. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Section 301(a) of the Federal Food, Drug, and Cosmetic Act (FDCA or Act), 21 U.S.C. 331(a), prohibits, inter alia, the introduction into interstate commerce of any misbranded drug. Under Section 503(b)(1) of the Act, 21 U.S.C. 353(b)(1), a drug is misbranded if it is a prescription drug that is dispensed without a prescription.[1] Section 303(a) of the FDCA, 21 U.S.C. 333(a), makes it a misdemeanor to commit one of the prohibited acts set forth in Section 301(a), 21 U.S.C. 331(a). If Section 301 is violated "with the intent to defraud or mislead," then under Section 303(b) of the FDCA, 21 U.S.C. 333(b), the offense is a felony.[2]

2. The evidence at trial is summarized by the court of appeals. Pet. App. 4a-6a. It showed that petitioner distributed anabolic steroids, androgenic hormones, and other drugs used by athletes to "increase muscle mass and thereby improve athletic performance." *Id.* at 4a. Because of the "many harmful side effects" of those drugs, the Food and Drug Administration (FDA) has not approved

---

[1] A prescription drug is a drug which "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug" (21 U.S.C. 353(b)(1)(B)), or which "is limited by an approved application under [21 U.S.C.] 355 * * * to use under the professional supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. 353(b)(1)(C).

[2] On April 22, 1988, the Prescription Drug Marketing Act of 1987, Pub. L. No. 199-293, 102 Stat. 95, became law and amended the FDCA in various respects. Section 333(a) and (b), however, were only redesignated as 21 U.S.C. 333(a)(1) and (2), respectively. § 7(b), 102 Stat. 99. Moreover, none of the provisions of the new Act became effective until July 21, 1988. § 8, 102 Stat. 100-101. Accordingly, all references to the FDCA in this brief are to the Act as codified prior to the adoption of the Prescription Drug Marketing Act of 1987.

them for such use, and they may be dispensed only on the prescription of a licensed physician. *Ibid.* Petitioner, however, distributed those drugs on the black market. In the spring of 1984, he obtained a wholesale drug distribution license from Florida state by misrepresenting that he was an established drug wholesaler in Alabama and would operate his business in that state. In fact, petitioner operated extensively in Florida, and he used various techniques (such as false names and mail drops) to avoid detection by federal and state officials. *Id.* at 5a.

In May 1986, a grand jury in the United States District Court for the Southern District of Florida returned an indictment against petitioner charging him with introducing into interstate commerce specified misbranded human prescription drugs with the intent to defraud and mislead. Before trial, petitioner moved to dismiss the indictment on the ground that it failed sufficiently to specify the charged offenses. The district court denied the motion. Thereafter, petitioner moved to bar the government from presenting evidence that petitioner had acted with the intent to defraud or mislead, within the meaning of 21 U.S.C. 333(b), by distributing the steroids in a manner that would avoid detection by the FDA or Florida regulatory agencies. Petitioner argued that Section 333(b) made it a crime only to defraud or mislead the ultimate consumer. The district court denied the motion on the ground that Section 333(b) does not require the government to prove that a particular individual has been defrauded or misled. 4 R. 91. At trial, the court instructed the jury that it could convict petitioner if he distributed the drugs with the intent to defraud or mislead the federal government or a state regulatory agency as well as "natural persons." Pet. App. 7a.[3] Petitioner was convicted on those counts in the indictment.

---

[3] The court instructed the jury that "[i]f you conclude from the evidence as a whole that there was an intent to defraud or mislead any

3. On appeal, petitioner argued that Section 333(b) should be limited to defrauding or misleading consumers, rather than governmental regulatory agencies. The court of appeals rejected that claim, ruling that "the structure of the statutory scheme, the purpose of the statute, and the case law persuade us that Congress meant to encompass conduct intended to defraud government enforcement agencies." Pet. App. 10a.[4] Petitioner also renewed his claim that the indictment failed to identify the offenses charged against him with sufficient particularity. The court of appeals rejected that claim without discussion. *Id.* at 16a.

ARGUMENT

1. Petitioner contends (Pet. 10-15) that the court of appeals misread the FDCA by permitting him to be convicted of a felony violation of the Act for defrauding or misleading a governmental regulatory agency, rather than a consumer. The court of appeals' decision, however, is consistent with the text and fundamental purposes of the Act.

Section 333(a) of Title 21 makes it a misdemeanor to violate any provision of 21 U.S.C. 331, while Section 333(b) makes it a felony for any person to violate Section 331 "with the intent to defraud or mislead." Petitioner

---

one of the entities, that is, the natural persons, State Agency, or Federal Government Agency, . . . then you may consider that the necessary intent has been proved." Pet. App. 7a.

[4] The court of appeals also noted that the evidence established petitioner's knowledge that his immediate customers "bought for the purpose of resale" and that there was "sufficient evidence for the jury to find that [petitioner] intended to defraud those unknown third persons to whom [petitioner's customers] would resell the drugs." Pet. App. 8a-9a.

concedes (Pet. 6) that he ran a black market steroid business in a way that both violated Section 331 and was calculated to avoid detection by federal and state regulatory authorities.[5] That is sufficient under Section 333(b), which does not require the government to prove that particular consumers were injured by the scheme.[6] Defrauding or misleading a federal or state regulatory agency also violates that section by preventing the government from carrying out a lawful regulatory function. Cf. *Hammerschmidt* v. *United States*, 265 U.S. 182, 188 (1924) ("To conspire to defraud the United States means primarily to cheat the government out of property or money, but it also means to interfere with or obstruct one of its lawful governmental functions by deceit, craft or trickery, or at least by means that are dishonest."). Moreover, treating petitioner's deception as a felony violation is consistent with the FDCA's underlying purpose. The Act established a comprehensive regulatory scheme governing the interstate distribution of drugs in order to enable the FDA to protect "the lives and health of people which, in the circumstances of modern industrialism, are

---

[5] As the court of appeals explained, "[d]uring this period, [petitioner] took various actions to avoid detection. He moved from state to state frequently. He used mail drops rather than his home address when mailing drugs to customers. He repeatedly used false names. He mislabeled his packages as vitamins and 'Herbalife products'. He hired surrogates to pick up and deliver the packages to carriers. He discussed methods of avoiding detection with his customers. * * * In an attempt to obtain a Florida drug wholesaler's permit in the spring of 1984, [petitioner] made affirmative misrepresentations to Florida state drug authorities." Pet. App. 5a.

[6] In fact, the court of appeals found that the evidence was sufficient to establish that petitioner intended to defraud the ultimate consumers of the steroids (Pet. App. 8a-9a), and petitioner does not challenge that finding in this Court.

largely beyond self-protection." *United States* v. *Dotterweich*, 320 U.S. 277, 280 (1943). Deceiving the FDA therefore harms the public by defeating the agency's ability to prevent the unlawful distribution of misbranded drugs.

That construction of Section 333(b) is also consistent with the Act as a whole. As the court of appeals explained (Pet. App. 10a-11a), several subsections of Section 331 prohibit various actions that immediately affect only the government, such as subsection (p), which prohibits failing to register with the FDA or supplying it with certain information. Petitioner's reading of the FDCA would render the felony provision of the Act wholly inapplicable to such conduct, even though Congress clearly intended to make a violation of subsection (p) undertaken with intent to defraud or mislead a felony under Section 333(b). Petitioner's construction of the Act is therefore inconsistent with the "well-settled rule of statutory construction that all parts of a statute, if at all possible, are to be given effect" (*Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 633 (1973)), and with the Court's admonition in cases interpreting the misdemeanor section of the FDCA (21 U.S.C. 333(a)), that its enforcement provisions should be liberally construed in order to effectuate its remedial purposes. *United States* v. *Dotterweich*, 320 U.S. at 284; *United States* v. *Sullivan*, 332 U.S. 689, 692-693 (1948). Finally, petitioner has cited nothing in the legislative history of the Act that stands as "the most extraordinary showing of contrary [congressional] intentions" necessary to deprive the text of the FDCA of its plain meaning. *Garcia* v. *United States*, 469 U.S. 70, 75 (1984).

Petitioner errs in asserting (Pet. 12-14) that the decision below conflicts with the decisions of several other courts of appeals.[7] Most of the cases cited by petitioner do not

[7] Petitioner also errs in claiming (Pet. 14) that the decision below conflicts with *United States* v. *Dotterweich*, 320 U.S. 277 (1943),

refer to this question at all.[8] Moreover, several other courts of appeals have upheld convictions under analogous statutes in similar circumstances. See *United States* v. *Cattle King Packing Co.*, 793 F.2d 232, 237-238 (10th Cir.), cert. denied, 479 U.S. 985 (1986) (upholding convictions for violations of the Federal Meat Inspection Act, 21 U.S.C. (& Supp. IV) 601-624, 661-680,[9] where the defendants sought to avoid the inspection of spoiled meat by federal inspectors); *Bachrack* v. *United States*, 75 F.2d 824, 824-825 (5th Cir. 1935) (stating that 18 U.S.C. 472, which prohibits possession of counterfeit internal revenue stamps, "uses the comprehensive term 'with intent to defraud' for the very purpose of making it immaterial whether the offender intended to defraud the government or some particular individual"); Pet. App. 13a-14a (collecting cases). To our knowledge, the only other decision that has referred to this issue is *United States* v. *Haga*, 821 F.2d 1036 (5th Cir. 1987). Although the court criticized the government's theory that defrauding a government agency rather than a consumer could violate 21 U.S.C. 333(b), that discussion was dicta, as the court itself recog-

---

United States v. *Sullivan*, 332 U.S. 689 (1948), and *Kordel* v. *United States*, 335 U.S. 345 (1948). None of those cases addressed this question.

[8] The decisions in *United States* v. *Jamieson-McKames Pharmaceuticals, Inc.*, 651 F.2d 532 (8th Cir. 1981), cert. denied, 455 U.S. 1016 (1982); *United States* v. *Abbott Laboratories*, 505 F.2d 565 (4th Cir. 1974), cert. denied, 420 U.S. 990 (1975); *United States* v. *Barnett*, 587 F.2d 252 (5th Cir.), cert. denied, 441 U.S. 923 (1979); and *United States* v. *Dr. David Roberts Veterinary Co.*, 104 F.2d 785 (7th Cir. 1939), do not mention this issue at all.

[9] The Federal Meat Inspection Act, which is modeled on the FDCA, makes any violation a misdemeanor and provides for enhanced felony punishment "if such violation involves intent to defraud." 21 U.S.C. 676(a).

nized (821 F.2d at 1044 n.17).[10] The decision below therefore does not conflict with *Haga*.[11]

2. Petitioner's fact-bound challenge to the sufficiency of the indictment also does not warrant further review. An indictment is sufficient if it contains the elements of the charged offense, fairly informs the accused of the charge against which he must defend, and enables him to plead an acquittal or conviction as a bar to a future prosecution for the same offense. *United States* v. *Bailey*, 444 U.S. 394, 414 (1980); *Hamling* v. *United States*, 418 U.S. 87, 117

---

[10] *Haga* reversed the defendant's conviction due to a variance between the charges in the indictment and the government's proof at trial. He was charged with conspiring to commit an offense against the United States, but was convicted of conspiring to defraud the United States. 821 F.2d at 1045-1046. Although the court criticized (*id.* at 1044-1045 n.17) the government's theory, that issue was not briefed in that case. That criticism, moreover, appears to be based on a misunderstanding of the government's theory. The court believed that, under the government's theory, "only inadvertent (or publicly announced) violations of section 331 would be misdemeanors, because all conscious (and not publicly confessed) violations would necessarily involve a deliberate evasion of established regulatory systems." 821 F.2d at 1044-1045 n.17. However, the government has never argued that any willful violation of Section 331 is a felony; only those violations designed to defraud or mislead would be felonies. In August 1987 we filed a motion asking the court in *Haga* to modify its opinion. Our motion is still pending.

[11] Presently before Congress is H.R. 5210, the Omnibus Drug Initiative Bill, 100th Cong., 2d Sess. (1988). A provision of that bill (§ 10019) would make it a crime, punishable by up to three years' imprisonment and a fine, to distribute or possess with the intent to distribute any anabolic steroid other than for the treatment of disease pursuant to a physician's order. 131 Cong. Rec. H7906, H7908 (daily ed. Sept. 22, 1988). The bill was passed by the House and is currently before the Senate. We will, of course, advise the Court if that bill becomes law.

(1974). The indictment here is sufficient under that standard. It virtually tracks the text of the Act, and it expressly sets forth in each count the drug that was misbranded, the manner in which it was misbranded, the date of its introduction into interstate commerce, and its intended recipient. Additional specificity is not required. See *Hamling* v. *United States*, 418 U.S. at 117-118 (citation omitted) (" 'Undoubtedly the language of the statute may be used in the general description of an offence, but it must be accompanied with such a statement of the facts and circumstances as will inform the accused of the specific offence, coming under the general description, with which he is charged.' ").

Petitioner objects (Pet. 15-21) that the indictment did not identify the party whom he intended to defraud or mislead when he distributed the misbranded drugs into interstate commerce. As explained above, however, Section 333(b) requires only that petitioner have acted with the intent to defraud when he distributed the steroids; it does not demand that the government prove that an identifiable victim of petitioner's scheme was injured. Indeed, petitioner concedes (Pet. 18) that the indictment contained the essential elements of the charge of violating 21 U.S.C. 331(b). That is sufficient, because it is well settled that an indictment need not "allege in detail the factual proof that will be relied upon to support the charges." *United States* v. *Crippen*, 579 F.2d 340, 342 (5th Cir. 1978). Accord, *e.g.*, *United States* v. *Lavergne*, 805 F.2d 517, 521 (5th Cir. 1986); *United States* v. *Castor*, 558 F.2d 379, 385 (7th Cir. 1977), cert. denied, 434 U.S. 1010 (1978); *United States* v. *Bernstein*, 533 F.2d 775, 786-787 (2d Cir.), cert. denied, 429 U.S. 998 (1976).[12]

[12] This case is similar to *Barbee* v. *United States*, 392 F.2d 532 (5th Cir.), cert. denied, 391 U.S. 935 (1968). There, the defendant was charged with the possession of counterfeit currency with the intent to

In any event, petitioner was fully aware of the parties whom the government alleged that he intended to mislead. Almost three months before the start of trial, the government stated in a memorandum in opposition to petitioner's motion to dismiss the indictment that "the user or customer, the Florida Board of Pharmacy, and the Food and Drug Administration were all intentionally defrauded and misled by defendant Bradshaw." 1 R. Doc. No. 37, at 10 n.4. The fact that petitioner was aware of the government's position is confirmed by his motion in limine, in which he sought to prevent the government from presenting evidence that he sought to defraud or mislead federal and state authorities. See Pet. App. 7a. Because petitioner was fully aware of the government's theory of the case, further review of his claim is not warranted.[13]

---

defraud, in violation of 18 U.S.C. 472. The defendant argued that the indictment was insufficient because it failed to identify the victim of his counterfeiting scheme. The court held that it was unnecessary for the indictment to contain such an allegation because the act did not require the government to prove that a particular victim had been defrauded. 392 F.2d at 539.

[13] The specificity of the indictment is also sufficient to enable petitioner to plead his conviction in this case as a bar to any future prosecutions for the same offenses. See *Russell* v. *United States*, 369 U.S. 749, 764 (1962) (in a prosecution for refusing to testify before Congress, "[s]ince the indictments set out not only the times and places of the hearings at which the petitioners refused to testify, but also specified the precise questions which they then and there refused to answer, it can hardly be doubted that the petitioners would be fully protected from again being put in jeopardy for the same offense"). Petitioner may also rely on the record developed in this case if necessary to assert a double jeopardy claim. 1 C. Wright, *Federal Practice and Procedure*, § 125, at 365 (2d ed. 1982) ("It has long been the rule that the entire record of the proceedings, and not the indictment or information alone, may be referred to if there is a claim that a subsequent prosecution constitutes double jeopardy," citing, *e.g.*, *Russell* v. *United States*, 369 U.S. at 764; *Bartell* v. *United States*, 227 U.S. 427, 433 (1913)).

CONCLUSION

The petition for a writ of certiorari should be denied.
Respectfully submitted.

CHARLES FRIED
Solicitor General
JOHN R. BOLTON
Assistant Attorney General
DOUGLAS N. LETTER
GERALD C. KELL
Attorneys

OCTOBER 1988

U.S. GOVERNMENT PRINTING OFFICE: 1988—241-699/60706